APL CLINICAL TRIALS & RESEARCH: WORKING PRACTICE

V1.0, May 10, 2024

APL Edmonton Zone Clinical Trials and Research (CT&R) Organization & Contact Information

	CT&R Technologist II's	CT&R Lab Assistants
Staff	3 Tech II's	10-12 Lab Assistants
Shared email address	APL.EZclinicaltrials@albertaprecisionlabs.ca	ACB.labclitr@ahs.ca
Contact for the following	• Lab manual updates/amendments • Memos from Sponsors or Central Labs regarding changes in processing or shipping • SIV meeting requests • Billing queries • General questions regarding study application, study setup, requisitions, etc.	• Requests for temperature charts and calibration records • Central Lab queries – missing samples, tracking information, etc.
Availability	Primary site: **Cross Cancer Institute Lab** • Monday-Friday 0730-1545hr	**Cross Cancer Institute Lab:** • Room 1468, CCI • Monday-Friday 0730-1545hr • Saturday 0730-1545hr • Ph: 780-432-8258 **UAH Touchdown Site:** • Room 4B2.10, WMC, UAH • Monday-Friday 0730-1545hr • Ph: 780-407-1131
Certification available	• GCP and TDG Air certificates Note: there is no additional charge to trials/studies for GCP and TDG certification. If further training is required, additional charges will apply.	• TDG Air certificates Note: CT&R Tech II's sign delegation and training logs on behalf of all CT&R Lab Staff. CTLA certificates are available to view as required.
Operational Information for Coordinator and Monitors	• CT&R: Operational Information (CCI and UAH Touchdown) for Coordinators and Monitors information provided on page 7	

Pre-NACTRC Application Resources

- Provincial Price List (on InSite)
- NACTRC website
- EPIC Procedure Catalogue with linked specimen information
- Shared email addresses listed on page 1

Research Study Workflow (further explanation of each step below)

1. **NACTRC Application**
2. **Research Agreement created and draft requisitions issued**
3. **Research Agreement reviewed and signed**
4. **APL Operational Approval**
5. **NACTRC AA**
6. **Delegation and training logs signed by APL CT&R/ SIVs attended**
7. **Items required for APL CT&R to provide final Research requisitions**
8. **Final requisitions issued**
9. **Samples collected, processed, stored, and shipped**
10. **Amendments and updates**
11. **Billing**
12. **Monitor visits/SIVs**
13. **Queries**
14. **Provision of Lab Documents**
15. **Study Closure**
16. **Operational/Miscellaneous Information**

1. **NACTRC Application:** PI/Coordinator requests Operational Approval from Alberta Precision Laboratories
   - **Local Lab only option** – Local lab tests are analyzed and resulted by APL. A Central Lab manual is not required if the study only requires local lab testing.
     - Local Lab Above Standard of Care testing refers to testing that is performed for study only and is not part of the patient's regular clinical care or is above the frequency of the patient's regular clinical care.
   - **Central Lab Testing required (local lab testing may or may not also be part of the study requirements) -** A Central Lab manual must be uploaded. CT&R is unable to proceed without Lab Manual being provided

- Upload manuals with study specific information only. Do not upload generic Lab manuals (i.e.: Generic Q2 Manual)
- NACTRC application contains a series of questions that populate the information into the Operational Approval (OA) form
- Lab will refer to the study as the name entered under "Protocol Acronym" in NACTRC
  - If no protocol acronym is provided, Lab does not assume an abbreviated name and will contact the Coordinator to confirm

2. **Research Agreement created and draft requisitions issued:**
   - APL CT&R Technologist reviews the protocol, OA form and lab manual(s) to create a research agreement and draft requisitions
   - Costing and approval from testing departments may be required
   - Draft requisitions will be emailed to the Study Coordinator and should be reviewed to confirm the requirements of the study have been met
   - CT&R will reach out to Study Team with questions pertaining to study setup/feasibility

3. **Research Agreement is reviewed**
   - Research agreement is reviewed, signed by Study Team, and uploaded back into NACTRC

4. **APL Operational Approval**
   - APL CT&R provides operational approval for the lab portion of the study
     - APL CT&R is unable to approve OA without signed RA uploaded into NACTRC

5. **NACTRC Administrative Approval**
   - NACTRC AA indicates that all departments have provided operational approval, ethics has been provided, and all documents required by NACTRC have been received (i.e. MTA, Data Disclosure)

6. **Delegation and training logs signed by APL CT&R/ SIVs attended**
   - One of the APL CT&R Tech IIs will:
     - Sign delegation log on behalf of APL CT&R
     - Sign training log on behalf of APL CT&R
     - Attend SIV if required (up to 30 minutes in duration). Virtual SIV preferred.
   - APL CT&R is unable to access study-specific portals due to the number of studies facilitated by APL
   - Paper logs can be sent to CCI via courier from Touchdown or emailed to CT&R Tech II shared email. Technologist will sign and scan, as well as send original "wet" copy back to Study Coordinator via courier back to Touchdown. Study Coordinator will be contacted when log is ready for pickup.

- Coordinator can also bring logs to CCI to be signed, with prior confirmation of appointment via Technologist shared email

7. Items required for APL CT&R to provide final Research requisitions

For APL CT&R to provide final research requisitions, the following items must be received:

- NACTRC AA
- Billing number: functional center (if not provided in NACTRC AA), speed code, or indication to direct bill
- Outstanding questions related to the collection, processing, storage, and shipping of samples answered/resolved
- Study supplies received
    - Lab supplies should be dropped off by Study Coordinator to Clinical Trials (CCI Room 1468 or the marked area in hallway outside of Room 4B2.10/Touchdown). Ensure all kits are removed from boxes before dropping off.
    - Clearly label with RES or CCLT number on outside of all boxes, packages, envelopes, etc.
    - Inform CT&R Staff if refrigerated or frozen items are included in the supplies
    - Do not have Central Lab ship supplies directly to CT&R as non-lab supplies are often included in shipments
    - Coordinator is responsible to know what has been sent to Clinical Trials
    - Clinical Trials will inventory once received
- Coordinator must indicate if study will not be supplying shipping boxes. Lab can supply and charge the study for boxes.
- Waybill or FedEx account number
    - Preferred courier is FedEx (APL has FedEx Ship Manager and daily scheduled pick-up)
    - Sticker waybills are accepted provided account information is on the waybill (require account + Internal reference + Recipient or Third Party Pay)
    - Account number provided via email (require account + Internal reference + Recipient or Third Party)
    - Other Couriers are accepted (Marken, World Courier, QuickStat) but not preferred
        - Additional Handling charge applies for non-FedEx courier

8. Final Requisitions issued:

- PDF versions of the final requisition(s) will be emailed to the Study Coordinator
- Research Kit requisitions contain the current Lab Manual version on top left hand side
- Issuing of the final requisition indicates that the study is live in Lab and samples can be collected

9. Samples collected, processed, stored, and shipped

Collection, Processing and Storage:

- EPIC: Research kit order to be placed and signed prior to collection in Connect Care
  - For Study Teams that do not have Connect Care access, Lab will place Research Kit order at the time of collection or at the time of receipt if not collected by Lab
- Reference Connect Care document "Clinical Trials and Research Sample Labelling or Research Kits" for sample and requisition labeling requirements
- Aliquot tubes must be labeled prior to drop-off in Lab
- Sample Deficiency form may be required if information is missing from the requisition. Study Coordinator will be contacted by Lab to sign form if required

Shipping:

- Completed requisitions are sent to Coordinator once samples are shipped
- Requests for shipping information (tracking #) and/or shipping notifications are subject to a Handling Fee
- Samples must be received in the UAH Clinical Trials and Research lab (4B2.10) by 1300hr for same day shipping. CCI samples must be received in Laby 1330hr for same day shipping. The complexity of the shipping requirements may impact ability to ship same day.

10. Amendments and updates

- Send electronic copy of updated protocol or manual to Technologist shared email
- Each document is subject to an amendment fee

Protocols

- Protocols that do not contain lab related updates do not need to be reviewed by Lab
- Note to File available: Protocol Review

Central Lab Manual/Processing information/Memos

- Lab manuals are reviewed and updated requisitions are provided via email
- Requisitions are always updated for Lab Manual revisions, as the manual version is recorded on the requisition
- Note to File available: Acknowledgement of Lab Manual review/ Updated APL requisitions serve as Lab Manual training

11. Billing

- Research invoices are generated in two ways:
  - Invoices generated from Epic encompass all patient-centric research kit billing, as well as above standard of care testing performed by APL
  - Non patient-centric billing (i.e. study setup fees, amendment review fees, batch packaging charges, etc.) is entered into a spreadsheet which is attached to the invoice

- Study Teams are responsible for completing Research Billing Review in Epic for all studies with an RSH record, and submission of payment in a timely manner
- Billing queries should be submitted within 3 months of receiving invoice

12. Monitor visits/Site Initiation Visit/Site Selection Visit

- Book a 30-minute time slot for both virtual and in-person meetings
  - In person visits to CCI require sign in in binder in Administrative Office Rm 1466
- Indicate in the invite if access to specific documents is required
  - Logs, equipment charts, and calibrations can be provided ahead of meeting
  - APL allows external clients to view SOPs, but not make copies as these are proprietary documents

13. Queries

Queries can be sent as follows:

Technologists shared email: APL.EZclinicaltrials@albertaprecisionlabs.ca for the following:

- Lab manual updates/amendments
- Memos from Sponsors regarding changes in processing or shipping
- SIV meeting requests
- Billing queries
- General questions

Clinical Trial Lab Assistants (CTLA) shared email ACB.labclitr@albertahealthservices.ca for the following:

- Temperature charts and calibration records
- Queries – missing samples, tracking information, etc.

14. Provision of Lab documents

- Regulatory documents and Notes to file are available on the NACTRC APL page: Alberta Precision Laboratories - NACTRC
  - Accreditation certificates for sites other than CCI and UAH are available upon request to the CT&R Tech II
- Temperature charts and calibration documents are available by request and are subject to a Handling Fee

15. Study Closure

- Please provide notification to CT&R Tech II's via email when the study has closed and/or there is no further involvement required from Lab
- If applicable, request Lab study documents at time of notification (i.e. processing logs)
  - Original versions of processing logs would be sent to Study Team

16. Operational/Miscellaneous Information

	Cross Cancer Institute	UAH Touchdown	Calibration Frequency
Freezer availability	-70°C & -20°C	-70°C & -20°C	Annually
Fridge availability	Yes	Yes	Annually
Room temperature centrifuge	Yes	Yes	Bi-annually
4°C centrifuge	Yes	Yes	Bi-annually
37°C Incubator	Yes	Yes	Annually
Requisitions	Sent to CTU daily through interdepartmental mail	Sent to Touchdown for Coordinators to pick-up (within 3 months)	
Delegation logs	Signed by CT&R Tech II		
Courier	• Samples are shipped from CCI Site • FedEx preferred via FedEx Ship Manager • Alternate acceptable couriers: Marken, QuickStat, World Courier		
Reference ranges	A comprehensive reference range document is not provided by APL. There are three ways for Coordinators to obtain the most current reference ranges: 1. Epic procedure catalog 2. Patient result report 3. InSite test directory		